



# Office Action Summary

Application No.

09/344,526

Applicant(s)

CHEE ET AL.

Examiner

Nancy Ogihara

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
  2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
  3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 20) ☐ Other: \_\_\_\_.

### DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1631**.

#### *Priority*

This application is a continuation of application 09/189,543, filed 11/10/98. This application claims priority to provisional application 60/090,473 filed 6/24/98, under 35 U.S.C. 119(e).

#### *IDS*

References 1-14 of the IDS (filed 12/6/99) appear to be missing from U.S. Application 09/189,543 where the documents were filed, and therefore have not been considered.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-14 are rejected under 35 U.S.C. 102(b) and 102(e) as being anticipated by Ekins et al (U.S. Patent No. 5,516,635).

Ekins et al disclose the placement of tagged microspheres onto a surface to form an array upon which multiple binding assays may be performed (see column 4, line 10 to column 5, line 40). Specifically, Ekins et al disclose microspheres distributed in discrete sites in array compositions (i.e. microtitre plates, see column 7, lines 59-60) comprised of a bioactive agent such as DNA (columns 8-9) and proteins (column 4, line 6), and identifier binding ligands and decoder binding ligands such as fluorescent labeled antibodies (see column 4, lines 26-28) which identify the bioactive agent. Ekins

et al also disclose bioactive agents with non-optical signatures such as with enzyme labels (see column 4, lines 10-12). Ekins et al further teach of using the microspheres to determine the presence of different analytes in a sample utilizing subpopulations of microspheres with different bioactive agents (see column 5, lines 28-39), using multiple fluorescent labels (see column 4, lines 26-27). Therefore, the disclosure of Ekins et al meet the limitations of the claims.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al (U.S. Patent No. 5,516,635) as applied to claims 1-14 above, in view of Vergne et al (Analytical Biochemistry, vol. 255(1), pp. 127-132 (1 January 1998)).

The teachings of Ekins et al are set forth above. Ekins et al further teach of using different fluorescent dyes associated with different binding ligands wherein the signals can be differentiated from one another (see column 5, lines 28-34). Ekins et al provide motivation for the selection of different optical dyes whose signals can be differentiated by, for example, a difference in pKa.

Vergne et al teach of utilizing the difference in pKa's of Oregon Green 488 and carboxyfluorescein (i.e. optical dyes) as reporter labels to distinguish different populations of cells (see abstract).

Given that 1) Ekins et al have taught of fluorescent tagged microsphere arrays wherein different subpopulations have differentiable fluorescent signals, and 2) that Vergne et al have taught of using fluorescent dyes with different pKa's, it would have prima facie obvious to one of ordinary skill in the art at the time the invention was made to fluorescent tag microsphere subpopulations with optical tags possessing different pKa's for the purpose of distinguishing different analytes within a sample. One of ordinary skill in the art would have been motivated to incorporate fluorescent optical dyes with different pKa's into the tagged microspheres of Vergne et al in view of Vergne et al teaching the advantages of being able to distinguish subpopulations of cells using fluorescent dyes with different pKa's.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/189,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass the placement of tagged microspheres onto a surface to form an array upon which multiple binding assays may be performed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Ogihara whose telephone number is (703) 308-9363. The examiner can be reached Monday-Friday from 8:30-6:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Woodward can be reached at (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1631 by facsimile transmission. Papers should be faxed to Group 1631 via the PTO Fax Center located in Crystal Park I. The faxing of such papers must conform with the notice published in the Official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Nancy Ogihara  
June 2, 2000

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER